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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR     | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

FORD, VANESSA L

ART UNIT

PAPER NUMBER

1645

DATE MAILED: 06/26/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/763,750

Applicant(s)

GORRINGE ET AL.

Examiner

Vanessa L. Ford

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 and 28-34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-20 and 28-34 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. Applicant's response to the Restriction requirement and election of Group I, claims 1-5, 6-8, 10-13 and 15-17, with traverse filed on March 22, 2002 is acknowledged. Claims 9, 14, 18-20 and 28-34 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being to a non-elected invention. The traversal is on the grounds that Groups I-VII relate to a single general inventive concept. Applicant urges that Group I is not anticipated by Nippon because the composition does not teach a bacterial Cu,Zn-SODs. Claim 1 is drawn to a pharmaceutical composition for vaccination comprising a bacterial Cu,Zn superoxide dismutase (Cu,Zn-SOD) of the dimeric type or fragment, variant or derivative of the Cu,Zn-SOD wherein antibodies raised against said fragment, variant or derivative also bind intact full length Cu,Zn-SOD or a nucleic acid coding for the Cu,Zn-SOD fragment, variant or derivative and a pharmaceutically acceptable carrier. Upon further consideration, the Examiner agrees with the Applicant in their assertion that Nippon does not disclose a bacterial Cu,Zn superoxide dismutase. Therefore a new lack of unity is set forth as follows:

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

***Election/Restrictions***

- Group I      Claims 1-5, 6-8, 10-13 and 15-17 are drawn to a pharmaceutical composition and vaccine comprising a bacterial Cu,Zn-superoxide dismutase or fragments, derivatives or variants thereof.
- Group II     Claims 1-5 and 6-8 are drawn to a pharmaceutical composition and vaccine comprising a nucleic acid that encodes a bacterial Cu,Zn-superoxide dismutase or fragments, derivatives or variants thereof.
- Group III    Claim 9 is drawn to a method of preparing a pharmaceutical composition comprising isolating a gene for a bacterial Cu,Zn-superoxide dismutase or fragments, derivatives or variants thereof.
- Group IV    Claims 10 and 13-14 are drawn to a pharmaceutical composition comprising an antibody to a bacterial Cu,Zn-superoxide dismutase or fragments, derivatives or variants thereof.
- Group V     Claims 18-20 and 31-33 are drawn to a method of treating an individual with a bacterial infection comprising administering bacterial Cu,Zn-superoxide dismutase or fragments, derivatives or variants thereof.
- Group VI    Claims 28-29 and 34 are drawn to a method of treating an individual with a bacterial infection comprising administering an antibody specific to a bacterial Cu,Zn-superoxide.

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Group VII      Claim 30 is drawn to a method of treating an individual with a bacterial infection comprising administering a nucleic acid encoding a bacterial Cu,Zn-superoxide.

3.      The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Group I lacks novelty under PCT Article 33(2) as being anticipated by Tabatabai et al, (*Vaccine*, 1994, *Volume 12, Number 10*). Tabatabai et al teach a mice were immunized with a various preparations containing saline, monophosphoryl lipid A and recombinant Cu,Zn-superoxide dismutase (rSOD)( page 920, 1<sup>st</sup> column). Tabatabai et al teach that rSOD was prepared from recombinant *Escherichia coli* (page 920. 1<sup>st</sup> column). Group I is the main invention in this application and it lacks novelty, therefore the other claims are not so linked by a special technical feature within the meaning of PCT Rule 13.2 so as to form a single inventive concept.

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4. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 308-4242.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (703) 308-4735. The examiner can normally be reached on Monday – Friday from 7:30 AM to 4:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached at (703) 308-3909.



Vanessa L. Ford  
Biotechnology Patent Examiner  
June 20, 2002



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